Policies for Adequacy and Timeliness of Follow-Up for Women with Abnormal Screening Results

Public Law 101-354 requires programs to take all appropriate measures to ensure the provision of necessary follow-up services required by women with abnormal screening results whose clinical services are paid for in whole or in part by NBCCEDP funds.

PC15: **Adequacy of Follow-up for Women with Abnormal Screening Results**

- A woman whose breast or cervical cancer screening was abnormal or suspicious must receive appropriate diagnostic procedures (as defined by the program's medical advisory committee) to arrive at a final diagnosis; and
- Women in whom breast or cervical cancer has been diagnosed must be referred for appropriate treatment.

PC.16: **Timeliness of Follow-up for Women with Abnormal Screening Results**

- The interval between initial screening and diagnosis of abnormal breast and cervical cancer screenings should be 60 days or less.
- The interval between diagnosis and initiation of treatment for breast cancer and invasive cervical cancer should be 60 days or less.
- The interval between diagnosis and initiation of treatment for cervical intraepithelial neoplasia should be 90 days or less.

UCCP PROTOCOL TO FOLLOW-UP AND MANAGE WOMEN WITH CYTOLOGICAL CERVICAL ABNORMALITIES AND CERVICAL CANCER PRECURSORS

(It is important to recognize that these guidelines should never be a substitute for clinical judgement. Clinicians need to practice clinician's discretion when applying a guideline to an individual patient since it is impossible to develop guidelines that apply to all situations.)

1. The Pap smear result is received from the laboratory and the result is:
"Negative"

- No follow-up needed. Client returns for annual screening. **CDC policy**: When a woman has had three consecutive, normal Pap tests documented within a 60-month period, the screening interval shall increase to once every three years.

- **Benign cellular changes identified as "negative"** – The previous Bethesda system included a category "benign cellular changes" to communicate findings due to a variety of factors, such as inflammation. This approach led to confusion at times for some clinicians who questioned whether the term indicates negative results or the need for follow-up. Now, such benign changes are clearly identified as "negative."

2. **"ASC" (Atypical Squamous Cells)**

The 2001 Bethesda System subdivides atypical squamous cells (ASC) into two categories: atypical squamous cells of undetermined significance (ASC-US) and atypical squamous cells, cannot exclude HSIL (ASC-H).

(a) Recommended Management of women with "ASC-US"

ASCCP recommendations: DNA testing for **high-risk** types of HPV should be performed using a sensitive molecular test. **All** women who test positive for high-risk HPV DNA should be

referred for colposcopic evaluation. Women with ASC-US who test negative for **high-risk** HPV DNA can be followed up with repeat cytological testing at 12 months. When a program of repeat cervical cytological testing is used, women with ASC-US should undergo repeat cytological testing (either conventional or liquid-based) at 4- to 6-month intervals until **two** consecutive "negative for intraepithelial lesion or malignancy" results are obtained. Women diagnosed with ASC-US or greater cytological abnormality on the repeat tests should be referred for colposcopy. After two repeat "negative for intraepithelial lesion or malignancy" cytology tests are obtained, women can be returned to routine cytological screening programs.

UCCP Follow-up Protocol for ASC-US

- **On May 2003 CDC approves the reimbursement of HPV DNA testing for high-risk only if used in follow-up of an ASCUS result from the screening exam. On December 2004, the UCCP Medical Advisory Board approved to follow-up these women with a 4 to 6 month repeated combining testing to minimize the number of unnecessary colposcopic examinations in women who have no disease.**

UCCP follow-up protocol:

- A letter and a copy of the lab result are mailed to the client within two days of receiving the Pap report.
- UCCP staff will determine if this is a first, or a repeated ASC-US for the client:

    (a) F**irst time result of ASC-US**, client is asked to return to a UCCP screening clinic in 4 to 6 months to have a repeated liquid-based Pap test. The screener should write in the lab slip that the client had an ASC-US in her conventional Pap test and that an HPV testing for high-risk strains needs to be conducted only if the liquid based Pap indicates an ASC-US. If the DNA- Hybrid test reflects low-risk HPV; client does not need a referral to see an OBGYN and resumes yearly follow-up. If the result indicates high-risk HPV, the client receives a paid referral to see an OBGYN.

    (b) History of repeated **ASC-US** in a two-year follow-up period, the patient should be referred to an UCCP OBGYN for additional evaluation. A letter and a copy of the Pap result are mailed to the client (letter #17). The client should also be contacted within the next three days by the follow up coordinator, who will complete the upper part of Pelvic/ Cervical Referral form and fax or mail to the UCCP OBGYN. The case manager or follow up coordinator is expected to arrange for an appointment and call the client the day before to remind the client of her appointment with the physician.
- For further follow-up see follow up for LSIL and HGSIL below.

(b) Recommended management of women with “ASC-H”

(The recommended management of women with ASC-H obtained either by conventional Pap or liquid-based cytology is referral for colposcopy evaluation)

- **UCCP follow up Protocol for ASC-H**
  On June 1, 2004, CDC policy authorizes the reimbursement for a LEEP or cold-knife conization of the cervix, as a diagnostic procedure to manage women with high grade squamous intraepithelial lesions (HSIL) in certain situations.

UCCP Follow-up Protocol

- The client should be contacted within the next three working days by the follow up coordinator, who will complete the upper part of Pelvic/ Cervical Referral form and fax or mail to the UCCP OBGYN. The follow up coordinator/case manager is expected to arrange for an appointment and call the client the day before to remind her of her appointment with the physician.
- For further follow up see follow up for LSIL and HGSIL down below.

(c) ASC-US in Special Circumstances

Postmenopausal women

(Providing a course of intravaginal estrogen followed by a repeat cervical cytology test obtained approximately a week after completing the regimen is an acceptable option for women with ASC-US who have clinical or cytological evidence of atrophy and no contraindications to using intravaginal estrogen.)

If the repeat result is "negative for intraepithelial lesion or malignancy," the test should be repeated in 4 to 6 months. If both repeat cytological test results are "negative for intraepithelial lesion or malignancy," the patient can return to routine cytological screening, whereas if either test result is reported as ASC-US or greater, the patient should be referred for colposcopy.

Immunosuppressed Women

Referral for colposcopy is recommended for all immunosuppressed patients with ASC-US. This includes all women infected with human immunodeficiency virus (HIV), irrespective of CD4 cell count, HIV viral load, or antiretroviral therapy.

Pregnant Women

It is recommended that pregnant women with ASC-US be managed in the same manner as non-pregnant women. The UCCP does not provide screening services to pregnant women.

3. "AGC" (Atypical Glandular Cells)

The 2001 Bethesda System classifies glandular cell abnormalities less severe than adenocarcinoma into three categories: atypical glandular cells, either endocervical, endometrial, or "glandular cells"not otherwise specified (AGC NOS); atypical glandular cells, either endocervical or "glandular cells" favor neoplasia (AGC "favor neoplasia"); and endocervical adenocarcinoma in situ (AIS). For atypical endometrial cells clients need to be referred for endometrial sampling, for all other subcategories clients need to have a colposcopy (with endocervical sampling) and endometrial sampling (if older than 35 or abnormal bleeding).

Recommendations for Managing Women with AGC or AIS: UCCP Policy

Initial Evaluation: Colposcopy with endocervical sampling is recommended for women with all subcategories of atypical glandular cells (AGC) (AGC "not otherwise specified [NOS] and AGC "favor neoplasia") and adenocarcinoma in situ (AIS). Management of women with initial AGC or AIS using a program of repeat cervical cytological testing is *unacceptable*.

Subsequent Evaluation or Follow-up: If invasive disease is not identified during the initial colposcopic workup, it is recommended that women with AGC "favor neoplasia" or endocervical AIS undergo a *diagnostic* excisional procedure. The preferred diagnostic excisional procedure for women with AGC "favor neoplasia" or AIS is cold-knife conization. If biopsy-confirmed CIN is identified during the initial workup of a woman with AGC NOS, management should be according to the 2001 Consensus Guidelines for the Management of Women with Cervical Histological Abnormalities. If no neoplasia is identified during the initial workup of a woman with AGC NOS, it is recommended that the woman be followed up using a program of repeat cervical cytological testing at 4- to 6-month intervals until 4 "negative for intraepithelial lesion or malignancy" results are obtained, after which the woman may return to routine screening

UCCP follow up Protocol for AGS

- A letter and a copy of the lab result are sent to the woman within two business days from the date that the Pap report is received (letter #8).
- The client should be contacted within the next three business days by the follow up coordinator, who will complete the upper part of Pelvic/ Cervical Referral form and fax or mail to the UCCP OBGYN. The follow up coordinator/case manager is expected to arrange for an appointment with the physician and make a reminder call the day before of her appointment.
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4. "Low Grade SIL (Squamous Intraepithelial Lesion)"

(Approaches that previously have been recommended for managing women with LSIL include repeat cytological testing or colposcopy. In some clinical settings, patients with LSIL are routinely followed up using cytology alone, without an initial colposcopic evaluation. The rationale for this is that the majority of women with LSIL have either no cervical lesion or CIN I, the majority of which spontaneously regress without treatment or are completely excised with a cervical biopsy. However, follow-up cytological studies have usually had high rates of loss to follow-up, a 53% to 76% likelihood of abnormal follow-up cytology results requiring eventual colposcopy, and a small but real risk of delaying the identification of invasive cancers. In contrast, referring all women with LSIL for colposcopy allows women with significant disease to be rapidly identified. Several approaches, including HPV-DNA testing and LEEP, do not appear to be useful for the initial management of women with LSIL)

(a) ASCCP Recommendations for Managing Women With LSIL

- Colposcopy is the recommended management option for women with LSIL. Subsequent management options depend on whether a lesion is identified, whether the colposcopic examination is satisfactory, and whether the patient is pregnant. The routine use of diagnostic excisional procedures such as LEEP or ablative procedures is unacceptable for the initial management of patients with LSIL in the absence of biopsy-confirmed CIN.

UCCP Follow-up Protocol for LGSIL

- Attempt to contact the client upon receipt of the low-grade results or at least within three business days after receiving the Pap results.
- If unable to contact the client, a letter is sent to the client with a copy of the Pap test is included.
- UCCP staff arranges a conference call with the client and UCCP OBGYN office staff to make an appointment.

- The case manager should assist the client coordinating the delivery of specific services to enhance compliance with physician appointments. Services such as translators, transportation and day care.
- The upper part of the Cervical/Pelvic Referral form is completed and sent/faxed to client or referral physician. The coordinator should contact the client the day before to remind her of her appointment with the physician.
- If the physician has not submitted a referral form within one week following the appointment, follow-up calls are made to the physician and/or the client to determine compliance with doctor visit.
- If client showed up for her appointment contact the physician's office to request for visit notes and any pathology reports (if any).
- For no shows, two phone attempts should be made to encourage the client to make an appointment to see the physician.
- If, after at least two phone calls, the client has not complied with making an appointment or has cancelled her appointment more than once, a certified letter is mailed to the client.
- If a client has been contacted by two phone calls within an interval of one to two weeks (fifteen working days) and the UCCP has received a signed receipt indicating that a certified letter was received by the client but she has made no attempt to complete her work up, she will be considered to have **"refused follow up".**
- If, after making at least two phone call attempts within an interval of one to two weeks (fifteen working days) to contact a client, a letter should be sent by certified mail. After two phone calls (at least) without response and no documentation that the certified letter was received by the client, she will be considered to be **"lost to follow-up".**

(b) LSIL in Special Circumstances

Postmenopausal Women

In postmenopausal patients, follow-up without initial colposcopy is acceptable option using protocols of either follow-up with repeat cytological testing at 6 and 12 months with a threshold of ASC-US or greater for referral for colposcopy, or follow-up with HPV DNA testing at 12 months with referral for colposcopy if testing is positive. A course of intravaginal estrogen followed by a repeat cervical cytology test approximately a week after completing the regimen is acceptable for women with LSIL who have clinical or cytological evidence of atrophy, with a referral for colposcopy if a result of ASC-US or greater is obtained and there are no contraindications to using intravaginal estrogen. If the repeat cervical cytology test result is "negative for intraepithelial lesion or malignancy," cytological testing should be repeated in 4 to 6 months. If both repeat cytology test results are "negative for intraepithelial lesion or malignancy," the patient can return to routine cytological screening, whereas if either repeat result is reported as ASC or greater, the patient should be referred for colposcopy.

Adolescents

In adolescents, an acceptable option is follow-up without initial colposcopy using a protocol of repeat cytological testing at 6 and 12 months with a threshold of ASC for referral for colposcopy, or of HPV DNA testing at 12 months with a referral for colposcopy if testing is positive for high-risk HPV DNA.

Pregnant women

Many colposcopists believe that a cytology test result of HSIL in a pregnant patient requires special consideration. Pregnancy accentuates both normal and abnormal colposcopic findings, and clinicians may not obtain appropriate cervical biopsies out of concern of increased bleeding.

Although cervical biopsy during pregnancy is associated with an increased risk of minor bleeding, it has not been associated with increased rates of major bleeding or pregnancy loss in the large studies, and a failure to perform cervical biopsies pregnant women has been associated with missed cancers. Because of the risk of potential injury to the fetus, endocervical sampling is proscribed during pregnancy.
The UCCP does not provide screening exams to pregnant women.

5. Recommendations for the management of "High grade SIL"

(A cytological result of HSIL identifies a woman at significant risk for having CIN 2,3 or invasive cancer; therefore, colposcopy with endocervical assessment has traditionally been considered the best approach to managing these patients.)

UCCP Policy
As of July 1, 2004, a LEEP or cold-knife conization of the cervix, as a diagnostic procedure may be reimbursed by the UCCP, based on the recommendations stated in the paragraphs that follow, and according to the attached algorithm from the ASCCP recommendations on management of women with high grade intraepithelial lesions (HSIL).

If a LEEP or conization is required for treatment, the client should be enrolled in the Utah Medicaid Treatment Act.

UCCP Follow-up Protocol for HGSIL

- Attempt to contact the client upon receipt of high grade result or at least within three working days after receiving the Pap results.
- If unable to contact the client, a certified letter is sent to the client with a copy of the Pap test.
- UCCP staff will arrange a conference call with the client and the physician's office staff to make an appointment.
- The case manager should assist the client coordinating the delivery of specific services to enhance compliance with physician appointments, such as translators, transportation and day care.
- The upper part of the Cervical/Pelvic Referral form is completed and sent/faxed to client or referral physician. The original forms remains at the UCCP.
- If the physician referral form has not submitted the final report within one week following the appointment, follow-up calls are made to the physician and/or the client to determine compliance with doctor visit.
- If indeed the client complied with her appointment, contact the physician's office to request for visit notes and any pathology reports (if any).
- Clients that miss their appointments (no- shows): these cases should be handed promptly to the case manager for follow-up and coordination of services to enhance compliance. Proof of documentation shows record of at least two phone attempts made to the client to encourage her to make an appointment and see the physician. Case management service plan should have a detailed assessment of the client's needs and coordination of services provided.
- If, after at least two phone calls, the client has not made efforts to reschedule or have cancel her appointments more than once a certified letter is mailed to the client reminding her about her health and responsibilities with the program.
- If a client has received two phone calls within an interval of one to two weeks (fifteen working days) and has had a personal visit from the UCCP case manager and voluntarily states that she is not going to follow through she will be considered as **"refused to follow up".** The client should sign a "refusal form" once after all

efforts have been made to assist the client with compliance. The original form remains at the UCCP, the pink copy is sent to the LHD and the third copy is mailed to the physician for his/her records. A competent client who is unable to sign a document personally can sign through an agent or a relative in presence of the caseworker.

- A certified letter is made after making (at least) three phone calls attempts within an interval of one to three weeks (twenty-one working days) to contact a client without success. After proof of documentation of at least three phone calls without response and a mail receipt indicating that letter returned as undeliverable, the case is considered as **"lost to follow-up".**

6. "Adenocarcinoma and squamous cell Carcinoma"

- Upon receipt of this test results, a referral for an OBGYN should be made the same day (preferable) that results were obtained.
- At least three attempts should be made to contact the client upon receipt of the test results or at least within three working days.
- If unable to contact the client, a certified letter is sent to the client with a copy of the Pap test.
- UCCP staff will arrange a conference call between the client and the gynecology-oncologist to set up an appointment.
- Once a diagnosis of cervical cancer has been determined, the UCCP will ensure that clients that are eligible for (Breast and Cervical Cancer Medicaid Treatment Act) receive medically necessary health care services.
- Clients who do not qualify for Medicaid assistance and need treatment will receive assistance in getting treatment through charity care, donated services, and payment plans.
- The clinical coordinator along with the data team will evaluate the provision of services in a monthly basis (clinical monthly report).
- The clinical staff will follow up every case to completion.

7. "Atrophia with a recommendation to repeat Pap after a course of estrogen"

Occasionally the pathologist will recommend a course of estrogen for women with a high risk for cervical cancer (past history of abnormal Pap smears) and when a Pap specimen is not adequate (absence of endocervical cells) due to cervical atrophy. A course of estrogen is defined by "two to three weeks course of topical estrogen before the Pap test is repeated"

- A letter and a copy of the lab report are sent to the client within two days after receiving the Pap report (letter # 18A).
- The client should be referred to a non-UCCP health care provider, such as a private primary care provider (Physician, Advanced Practice Registered Nurses, Physician Assistants) for treatment.
- Once treatment is completed client should return to the cancer clinic for a repeat Pap (all this information should be included in the letter).
- The UCCP will follow-up according to results.

8. "Clients with results "satisfactory but limited by..." (Lack of endocervical cells)

- If the client has an actual Pap test proof of an "outside" ASCUS or UCCP records show a previous ASCUS results, client receives letter #18 where she is advised to return to a UCCP clinic to receive a Pap test.

- If a client's Pap smear is deemed "unsatisfactory" and has more than three of the following risks: exposure to DES, heavy smoker (at least one pack a day), history of dysplasia, positive for high risk-HPV multiple sexual partners, never and rarely screened, she will be advised to return to a UCCP clinic to receive a repeat Pap free of cost.
- The UCCP clinical team will follow-up accordingly.

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